

REMARKS

By the present Amendment, Claims 1-6 and 10-23 are pending. Claims 1-6 are original. Claims 7-9 have been cancelled. Claims 10-23 have been newly added by the present Amendment. Support for the present amendments, including new claims, may be found throughout the specification, including for example in the original claims, at page 5, lines 20-24 and page 16, line 9. No new matter enters by these amendments.

I. Restriction/Election

Applicants thank the Examiner for acknowledging Applicants' election with traverse of Group I. Applicants acknowledge the finality of the restriction requirement and maintain their traversal.

II. 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1, 2 and 5-6 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Office Action at page 3. The Examiner alleged that "[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *Id.* Applicants respectfully disagree with the Examiner's basis for rejection.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of 35 U.S.C. § 112, all things that are encompassed by the claims. Any contention otherwise contradicts established jurisprudence, which teaches that a patent may be infringed by

technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1989).

It is well-established law that claims “may be broader than the specific embodiment disclosed in a specification.” *Ralston-Purina Co. v. Far-Mar Co.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215 (C.C.P.A. 1981). Thus, in order for Applicants to describe the AMPK inhibitors encompassed by the claims, it is not required that every aspect of each and every AMPK inhibitor be disclosed. *In re Alton*, 76 F.3d at 1175 (if a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description requirement has been met).

The Examiner stated that “[t]o provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, *physical and/or chemical properties, functional characteristics*, structure/function correlation, methods of making the claimed product, *or any combination thereof.*” Office Action at page 4 (emphasis added). The Examiner further alleged that “the specification does not provide adequate written description for use of the claimed genus of AMPK inhibitors required to practice the currently claimed method because one skilled in the art *cannot structurally visualized* [sic] any functional generic ‘compound’ peptide or nonpeptide, small molecule, or biologically-derived material.” *Id.* (emphasis added). Applicants respectfully disagree.

Applicants submit that the specification provides distinguishing characteristics of the genus by setting forth physical and/or chemical properties and functional characteristics of the claimed subject matter. For example, Applicants have provided exemplary AMPK inhibitors such as Compound C and C75. Moreover, Applicants’ specification states for example that “[b]y ‘AMPK inhibitor,’ we mean a compound which inhibits AMPK as determined by the method described by Witters, et al., *Journal of Biological Chemistry*, 267, pp. 2864-2867 (1992).” As

such, the skilled artisan would be well aware of AMPK inhibitors that can be used in the claimed methods.

Further, as acknowledged by the Examiner, Applicants “. . . describe[s] on pages 2-3 that ‘C75 treatment inactivates and dephosphorylates AMPK’” Office Action at page 3. The specification also teaches that “[c]ompound C reduces pAMPK levels.” *See e.g.*, Specification at page 16, line 9. The Examiner further acknowledged that “[p]ages 6 and 16-17 then state that ‘administration of the AMPK inhibitor compound C, or the FAS inhibitor C75, provided significant neuroprotection in our model.’” Office Action at page 3. Additionally, the specification notes that “[i]n contrast, administration of the AMPK activator AICAR exacerbated stroke damage.” Specification at page 6.

Based on the foregoing, Applicants respectfully submit that a skilled artisan would recognize that Applicants were in possession of the claimed subject matter and have met the written description requirement. As such, the rejection of claims 1, 2 and 5-6 under 35 U.S.C. § 112, first paragraph is improper and withdrawal of this rejection is respectfully requested.

III. 35 U.S.C. § 102(b)

Claims 1-2 and 5-6 were rejected under 35 U.S.C. 102(b) as being anticipated by Tracey *et al* (hereinafter “Tracey”). *Id.* at page 5. Applicants respectfully traverse this rejection. Whatever else Tracey teaches, Tracey does not teach a method which “comprises administering a compound . . . , the compound being an AMPK inhibitor.” *See e.g.*, Claim 1. Rather, Tracey recites “administering . . . a combination . . . of an NHE-1 inhibitor and a second compound”. *See e.g.*, Tracey at abstract.

In Tracey, the second compound is at best selected from five generic classes of compounds, including “(a) a complement modulator, (b) a metabolic modulator, (c) an anti-apoptotic agent, (d) a nitric oxide synthase-related agent, and (e) an enzyme/protein modulator.” *See e.g.*, Tracey at abstract. Although a 5’ AMP-activated protein kinase (AMPK) inhibitor is

listed as one of a laundry list of possibilities of option (b) metabolic modulators, Tracey, unlike Applicants' specification, provides no data or support whatsoever for any possible neuroprotective activity of AMPK inhibitors.

Indeed, in light of the Hardie article (hereinafter "Hardie"), submitted by Applicants' May 5, 2011 Information Disclosure Statement, the skilled artisan would have no reason to believe that AMPK inhibition is in any way neuroprotective. Indeed, to the contrary, Hardie refers to a study by Kuramoto, suggesting that "AMPK activation is neuroprotective...." *See e.g.*, Hardie at abstract.

By contrast to Tracey's absence of any data, Applicants' specification provides that "[c]ompound C treatment causes a significant decrease in regional and total stroke volume." Specification at Figure 6. Applicants' specification also provides that "[c]ompound C reduces pAMPK levels and is neuroprotective." *Id.* at page 16, line 9. The specification further notes that "[r]eduction in pAMPK levels by the FAS inhibitor C75 is neuroprotective in stroke." *Id.* at page 17, line 9. Additionally, the specification states that "[i]n contrast, administration of the AMPK activator AICAR exacerbated stroke damage." Specification at page 6.

As such, Applicants respectfully submit that although the words AMPK appear in Tracey, unlike Applicants' specification, Tracey does not teach "[a] method of neuroprotection which comprises administering a compound to a subject ..., the compound being an AMPK inhibitor...."

Based on the foregoing, withdrawal of the rejection of claims 1-2 and 5-6 under 35 U.S.C. § 102(b) is respectfully requested.

IV. 35 U.S.C. § 103(a)

(a) Claims 1-3 and 5-6 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tracey further in view of Kim *et al* (hereinafter "Kim"). The Examiner acknowledged that "Tracey *et al* do not mention use of the AMPK inhibitors, compound C or

C75.” Office Action at page 6. Likewise, the Examiner acknowledged that “Ki[m] et al do not teach administration of C75 to subjects experiencing a stroke.” *Id.* Applicants thank the Examiner for these acknowledgements.

The Examiner contended that “[i]t would have been obvious to one of ordinary skill in the art at the time of filing Applicants’ invention to use the AMPK inhibitor of Kim in Tracey’s method of treating ischemia with AMPK inhibitors with a reasonable expectation of success.” *Id.* Applicants respectfully disagree with this contention. As noted above, whatever else Tracey teaches, Tracey does not teach a method which “comprises administering a compound ..., the compound being an AMPK inhibitor.” *See e.g.*, Claim 1. Likewise, Kim does not remedy this deficiency.

Further, in light of Hardie, one of ordinary skill in the art would not have combined Tracey and Kim with any reasonable expectation of success. Rather, the use of Kim in combination with Tracey constitutes impermissible hindsight in light of Applicants’ specification. As such, withdrawal of the rejection of claims 1-3 and 5-6 under 35 U.S.C. § 103(a) is respectfully requested.

(b) Claims 1-2 and 4-6 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Tracey further in view of Leon *et al.* (hereinafter “Leon”). The Examiner acknowledged that “Tracey et al do not mention use of the AMPK inhibitors, compound C or C75.” *Id.* Likewise, the Examiner acknowledged that “Leon et al do not teach administration of Compound C to subjects experiencing a stroke.” *Id.* at page 7. Applicants thank the Examiner for these acknowledgements.

The Examiner argued that “[i]t would have been obvious to one of ordinary skill in the art at the time of filing Applicants’ invention to use the AMPK inhibitor of Leon in Tracey’s method of treating ischemia with AMPK inhibitors with a reasonable expectation of success.” *Id.* Applicants respectfully disagree. As provided above, whatever else Tracey teaches, Tracey does not teach a method which “comprises administering a compound ..., the compound being an AMPK inhibitor.” *See e.g.*, Claim 1. Moreover, Leon does not remedy this deficiency.

Further, in light of Hardie, one of ordinary skill in the art would not have combined Tracey and Leon with any reasonable expectation of success. Rather, as with Kim, the Examiner's use of Leon in combination with Tracey constitutes impermissible hindsight in light of Applicants' specification. As such, withdrawal of the rejection of claims 1-2 and 4-6 under 35 U.S.C. § 103(a) is respectfully requested.

V. CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the present application is in condition for allowance and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5325 if any additional information is necessary for allowance.

Respectfully submitted,



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